

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

**Alza Corporation and Janssen Pharmaceuticals,
Inc.,**

Plaintiffs,

v.

Par Pharmaceutical, Inc.,

Defendant.

Civil Action No. 13-1104-RGA
(consolidated)

**Alza Corporation and Janssen Pharmaceuticals,
Inc.,**

Plaintiffs,

v.

**Osmotica Kereskedelmi es Szolgaltato Kft and
Osmotica Pharmaceutical Corp.,**

Defendants.

MEMORANDUM ORDER

Before the Court is Plaintiff's Motion to Strike Defenses and Dismiss Counterclaims Alleging Inequitable Conduct (D.I. 125) and related briefing. (D.I. 126, 132, 133, 137). Defendants have each filed Abbreviated New Drug Applications ("ANDAs") seeking to market generic versions of Plaintiffs' drug Concerta. Plaintiffs have alleged that the filing of these ANDAs infringes one or more claims of U.S. Patent No. 8,163,798 and U.S. Patent No. 8,629,179. Defendants counterclaimed that the patents are invalid and not infringed, and have

also asserted defenses and counterclaims of inequitable conduct. The inequitable conduct allegations are the subject of this motion. Plaintiffs assert that Defendants' inequitable conduct allegations have not been pled with particularity because the allegations do not identify "who" committed the inequitable conduct.

In order to establish inequitable conduct, an accused infringer must prove that a specific individual with a duty of candor to the PTO "misrepresented or omitted material information with the specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). Allegations of inequitable conduct must be pled with particularity. *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). "[T]o plead the circumstances of inequitable conduct with the requisite particularity under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Id.* at 1328. Plaintiffs assert only that Defendants did not adequately allege the "who" aspect of the pleadings. (D.I. 126 at 15-16 n. 9).

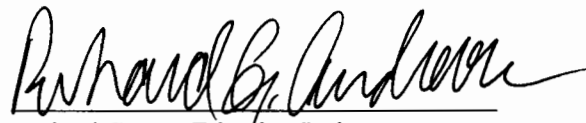
In support of their assertion, Plaintiffs point to Osmotica's repeated reference to "the Applicants," which is loosely defined as named inventors or identified inventors or one or more of their agents or attorneys or other persons involved in the prosecution of the applications including the Prosecution Attorneys. (D.I. 121 ¶ 74). Similarly, Plaintiffs point to Par's shifting use of "Alza," and "Alza, the named inventors, and individuals substantively involved in the preparation and prosecution of the applications." (D.I. 118 ¶ 6). Additionally, the Court notes that the paragraphs in Par's answer which specifically allege inequitable conduct do not particularly point out the "who." (D.I. 118 at 16 ¶¶ 30-31).

The Court agrees that Defendants have failed to adequately plead the "who" of the inequitable conduct allegations. However, the inadequacy of the pleadings has nothing to do with

any dearth of factual basis. The insufficiency of the present allegations is principally that they allege a mishmash of facts without sorting them out in relation to particular acts of particular individuals. The Defendants need to identify by name the individuals who did things constituting affirmative misconduct or contrary to the duty of candor, and material to the issuance of the patents, on particular dates, with the intent to deceive the PTO. A conclusory statement at the end of the pleadings that the facts are sufficient to allege inequitable conduct is not enough.

The Court grants the motion to dismiss the inequitable conduct counterclaims (D.I. 125), but with leave to amend within ten days.

Entered this 27th day of May, 2014.


United States District Judge